AUTHORITY: 21 U.S.C. 342, 360b, 371.

SOURCE: 40 FR 13942, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 556.1 General considerations; tolerances for residues of new animal drugs in food.

(a) Tolerances established in this part are based upon residues of drugs in edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug shall result in a conclusion either that:

(1) Finite residues will be present in the edible products—in which case a finite tolerance is required; or

(2) It is not possible to determine whether finite residues will be incurred but there is reasonable expectation that they may be present—in which case a tolerance for negligible residue is required; or

(3) The drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, has been shown to induce cancer in man or animal; however, such drug will not adversely affect the animals for which it is intended, and no residue of such drug will be found by prescribed methods of analysis in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal—in which case the accepted method of analysis shall be published or cited, if previously published and available elsewhere, in this part; or

(4) It may or may not be possible to determine whether finite residues will be incurred but there is no reasonable expectation that they may be present—in which case the establishment of a tolerance is not required; or

(5) The drug is such that it may be metabolized and/or assimilated in such form that any possible residue would be indistinguishable from normal tissue constituents—in which case the establishment of a tolerance is not required.

(b) No tolerance established pursuant to paragraph (a)(1) of this section will be set at any level higher than that reflected by the permitted use of the drug.

(c) Any tolerance required pursuant to this section will, in addition to the

toxicological considerations, be conditioned on the availability of a practicable analytical method to determine the quantity of residue. Such method must be sensitive to and reliable at the established tolerance level or, in certain instances, may be sensitive at a higher level where such level is also deemed satisfactory and safe in light of the toxicity of the drug residue and of the unlikelihood of such residue's exceeding the tolerance.

Subpart B—Specific Tolerances for Residues of New Animal Drugs

§ 556.34 Albendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of albendazole is 5 micrograms per kilogram of body weight per day.

(b) *Tolerances.* The tolerances for albendazole 2-aminosulfone (marker residue) are:

(1) *Cattle*—(i) *Liver (target tissue)*: 0.2 parts per million (ppm).

(ii) *Muscle*: 0.05 ppm.

(2) *Sheep*—(i) *Liver (target tissue)*: 0.25 ppm.

(ii) *Muscle*: 0.05 ppm.

(3) *Goat*—(i) *Liver (target tissue*): 0.25 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See § 520.45 of this chapter.

[64 FR 1504, Jan. 11, 1999, as amended at 73 FR 11027, Feb. 29, 2008]

§ 556.36 Altrenogest.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of altrenogest is 0.04 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine*—(i) *Liver (the target tissue).* The tolerance for altrenogest (the marker residue) is 4 parts per billion (ppb).

(ii) *Muscle.* The tolerance for altrenogest (the marker residue) is 1 ppb.

(2) [Reserved]

[68 FR 62007, Oct. 31, 2003]

§ 556.38 Amoxicillin.

A tolerance of 0.01 part per million is established for negligible residues of amoxicillin in milk and in the uncooked edible tissues of cattle.

[49 FR 45422, Nov. 16, 1984]

§ 556.40 Ampicillin.

A tolerance of 0.01 p/m is established for negligible residues of ampicillin in the uncooked edible tissues of swine and cattle and in milk.

§ 556.50 Amprolium.

Tolerances are established as follows for residues of amprolium (1-(4-amino-2-*n*- propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride):

(a) In the edible tissues and in eggs of chickens and turkeys:

(1) 1 part per million in uncooked liver and kidney.

(2) 0.5 part per million in uncooked muscle tissue.

(3) In eggs:

(i) 8 parts per million in egg yolks.

(ii) 4 parts per million in whole eggs.

(b) In the edible tissues of calves:

(1) 2.0 parts per million in uncooked fat.

(2) 0.5 part per million in uncooked muscle tissue, liver, and kidney.

(c) In the edible tissues of pheasants:

(1) 1 part per million in uncooked liver.

(2) 0.5 part per million in uncooked muscle.

[40 FR 13942, Mar. 27, 1975, as amended at 50 FR 18472, May 1, 1985]

§ 556.52 Apramycin.

A tolerance of 0.1 part per million is established for parent apramycin (marker residue) in kidney (target tissue) of swine. The acceptable daily intake (ADI) for total residues of apramycin is 25 micrograms per kilogram of body weight per day.

[62 FR 40933, July 31, 1997]

§ 556.68 Avilamycin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of avilamycin is 1.1 milligram per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for avilamycin is not required.

(c) *Related conditions of use.* See § 558.68 of this chapter.

[80 FR 61297, Oct. 13, 2015]